Experiences of leg bag users and emerging design priorities

Moody, L. and McCarthy, A.

Abstract

Purpose: The purpose of the study was to explore participant's experiences of urinary incontinence and leg bag use in order to identify priorities for product re-design.

Subjects and Setting: Twenty nine 29 leg bag users and 5 carers and healthcare professionals participated in the study. They were recruited through a UK hospital Trust and a UK wide charity for people with bladder and bowel control problems.

Design: The study employed a descriptive design with qualitative and quantitative elements to determine current experiences with urinary drainage leg bags and identify potential ways to improve their design.

Methods: Data collection occurred during semi-structured face to face and telephone semi-structured interviews.

Results: Thematic analysis revealed that leg bag design and performance influenced users' relationships, confidence and ability to socialize. The most significant issues related to leg bag use were reliable functioning without leakage, secure positioning and discretion when worn under clothing. All leg bag used reported experienced significant urine leakage due to usability issues with the leg bags.

Conclusions: Respondents identified a number of design issues with current leg bags that need to be addressed to improve the ease of use and overall experience when using leg bags for containing urinary output. The findings have been used to define design requirements for further development of leg bags and their component parts.

Keywords: Long-term urinary catheter, catheter drainage systems, leg bags, adults

Introduction

A leg bag is a urinary drainage device that is attached directly to an indwelling urinary catheter or external collecting device.[1,2] Measures of its effectiveness include its ability to reliably collect and store urine, and its ability to remain hidden when worn underneath clothing.[3] Regular use of a leg bag may disrupt daily activities and negatively influence physical and psychological well-being.[3-5] Failure of teh leg beg to store urine is associated with unreliable connections, leaking taps, and difficulty manipulating or emptying the leg bag resulting in urine leakage or spillage.[6,7] In addition, leg bags can be hard to conceal; they tend to bulge beneath clothing as they fill, and they are often associated with audible sloshing of urine.[5,8,9] The materials used for constructing leg bags can cause perspiration, leading to skin irritation and bag slippage.[10] Leg bags are frequently strapped to the leg to prevent excessive movement; however, straps may not adequately restrict movement, resulting in traction on the indwelling catheter or external leg bag (Figure 1).[7,11-13]

Innovation in leg bag design with a focus on ease of use is essential given the increasing number of individual who rely on leg bags for urinary drainage.[14] Users of leg bags have a variety of physical and mental capabilities, support needs, and lifestyles. The range of commercially available leg base should address these varied needs. This aim of this study was to explore experiences of persons using a leg bag, and identify ways in which the design of the products could be developed to improve the user experience.

Methods

The study employed a descriptive design adopting a largely qualitative approach. Semi-structured interviews were completed that enabled respondents to describe their experiences using leg bags for urinary drainage. Several questions required forced rsponses using a Likert type scale that enabled quantification and comparison of participant experiences in relation to their feelings of dignity. Research procedures were reviewed and

the study was granted ethical approval by the Coventry University Research Ethics Committee.

Study Procedures

Telephone and face-to-face interviews were completed by a single researcher (LM) with the participants using a standardized interview protocol. Open ended questions prompted respondents to describe their experiences with using leg bags for urinary drainage, loss of urinary containment, ease of leg bag use and associated components, and suggestions as to how existing products might be improved. While these items guided the interviews, they also enabled respondents to discuss issues raised by participants. Forced choice items were used to collect demographic information about participants and to allow some frequency data to be collected specific leg bag usage. Interviews lasted between 30 and 90 minutes. The discussions were recorded in detailed note form by the interviewer; interviews were not audiotaped.

Data Analysis

The investigator's notes were analyzed and data subjected to thematic analysis using an inductive approach by a second independent researcher.[15] Data were coded to identify relevant aspects; once a comprehensive set of codes were created; repeated patterns across the data set were identified to generate themes. The coding reliability was checked by the investigator and agreement reached about the main themes to be reported. These themes were then refined and illustrative quotations selected. Descriptive statistics were used to characterize demographic data.

Results

Thirty four persons participated in the study. Twenty nine respondents were regular leg bag users; 9 users were female and 20 were male, their age varied from 37 to 91 years (Table 1). The length of leg bag use varied from approximately 2 months to 30 years. Non-

leg bag user participants included 2 urologists, a urology nurse and 2 lay caregivers. Participant characteristics are summarised in Table 2. Indications for use of an indwelling urethral catheter, external collection device and associated leg bag were neurogenic bladder dysfunction, urinary retention, or refractory incontinence refractory to other interventions. Participants were asked to self-rate their dexterity and mobility (Figure 2). Several participants stated they required assistance at times.

Participants were asked to rate perceptions of dignity when using their leg bag on a scale of 1 to 10, where a score of 1 indicated little dignity and 10 indicated a great deal of dignity (Figure 3). Leg bag users reported positive perceptions of dignity when using leg bags (median 8; interquartile range 2). When asked to qualify their responses, most participants indicated that despite dissatisfaction with specific features of the leg bags, these devices offered greater dignity when compared to living without them. As one respondent noted, use of a lag bag is *"...degrading to use but million times better than wetting myself"*, and another stated "*without it* [leg bag] *life would be impossible*".

Nevertheless, all 8 leg bag users stated they experienced embarrassing or humiliating incidents when using a leg bag that negatively impacted their confidence. One participant noted that recovery from a leakage episode "*takes a while to restore confidence, about 2 weeks to overcome each disaster.*" Participants further observed that leakage incidents were typically related to a failure of the product's intended function (unintentional opening of the drainage port) or improper use of the product (failure to close the drainage port).

Use of a leg bag also affected participants' relationships, confidence and ability to socialize. One participant observed, *"I couldn't imagine being in a relationship with a leg bag and showing it to someone"*. The impact on participants' lives based on the qualitative analysis could be linked to a number of factors including gender, age, co-existing conditions, length of time being incontinent and whether they were in a continuing relationship at the

time of becoming incontinent. Daily activities affected by using a leg bag included swimming, sunbathing, gardening, going out for the whole day, playing football, running, and riding a bike. Respondents also reported that leg bag use influenced clothing choices.

Product Selection

Respondents described using a variety of leg bags. The most commonly used bags were produced by Bard Medical (Crawley, UK) Coloplast UK Ltd (Peterborough, UK) and Manfred Sauer UK (Northampton, UK). Six of the 34 participants (17.6%) indicated they were satisfied with the system they used at the time of their interview. The majority (27 out of 29 leg bag users) stated they had changed the brand of leg bag they used at least once owing to a variety of product design issues. The importance of being able to find improved products was perceived as essential to the ability of many participants to cope with their condition. As one participant stated, "*if I didn't find better products it would have destroyed me.*"

Analysis indicated that continence support varied based on the area of UK residence. Partcipants reported that the UK Bladder and Bowel Foundation, the Spinal Injuries Association, medical trade shows, industry representatives, and the internet served as sources of information about available leg bags and their use. Perceived barriers to identifying a more usable leg bag system included: lack of information about alternative products, the feeling of safety with a known product, the effort involved in making a change and reluctance to talk about their need for a leg bag and associated lower urinary tract symptoms.

Managing a Leg Bag

Most participants reported changing their leg bag every 5 to 7 days (range 2 to 10 days). Despite recommendations from the National Institute for Health and Care Excellence (NICE) about maintenance of a closed system for prevention of catheter-associated urinary tract infection, respondents note a urinary drainage system involving a leg bag cannot be

characterized as closed because of the need to regularly open the leg bag for drainage and switch to an overnight drainage bag in most cases. In addition, some users (n=5; 17%) reported washing out their bag daily.

Weaknesses associated with leg bag use included concerns about the bag were its capacity and level of discretion when worn under clothing. Respondents further acknowledged that these elements conflict to some extent. The storage capacity of available leg bags varies from 500 to 1500 ml. Some participants using smaller capacity bags were not aware that significantly larger ones were available (3/29; 10%). Leg bag users typically chose a larger capacity for the convenience of less frequent emptying, reduced carer dependence, and the reassurance that the bag was less likely to leak if a toilet could not be readily reached for emptying of the bag. Others explained that they had opted for a smaller capacity to aid discretion: *"..it's emptied frequently to ensure its not showing....I don't want it to bulge, so it is smaller and at the bottom of my leg where the trouser is wide"*.

Most leg bags used by respondents were described incorporated graduation markers that enabled the user to assess urine volume in the bag. Respondents observed that a clear bag is useful because it enables them to assess the color and volume of urine. Respondents noted that a leg bag that was at, or near capacity tended to create a bulge under clothing, leading to self-consciousness and more frequent emptying. A multi-chambered bag (where the urine is channelled into separate chambers to distribute it evenly across the width of the bag) was generally considered better at distributing the bulk of the bag and minimizing sloshing of urine. For more mobile users perceptions of urine sloshing around the bag as the wearer moves was viewed as a problem, particularly when the bag is positioned on the lower leg. As one respondent noted, "*If I can hear it, then so can other*s".

Eight participants stated that smell associated with the leg bag was an issue. It was a more common problem in summer, or when the user experienced a urinary tract infection.

The odor from leg bags was perceived as impregnating clothing by several users. In order to prevent this outcome, users reported changing leg bags as often as every other day.

Drainage Ports

All leg bag users reported experiencing urine leakage due to leakage from the drainage port at least once. Respondents reported multiple limitations associated with drainage port use, including the level of dexterity and strength required for operation and the risk of accidental opening. Often it was assumed by the user that they had made an error rather than a failing in the product design. As one user observed, "*I'm sure it's my own bloody fault*".

Accidental drainage port opening was associated with the port getting caught in a sock, or knocked against the other leg. Some reported accidental opening occurred once or twice, but others estimated it occurred as often as 3 to 4 times weekly. The use of a sleeve, tucking the tap in the sock to protect it from knocks and temporary fixes using whatever was at hand such as additional pieces of tubing were required. Leakage was also reported to occur when the user forgot to close the tap after emptying. In addition, respondents reported that some leg bags are packaged with the tap open, which is easily forgotten on initial use. Leg-bag users noted presence of a band on some drainage ports designed to reduce the possibility of the port being left open, but these were reported to be flimsy and weaken over time. Other issues included some twisting taps that did not provide clear cues that sufficient closure of the tap had been achieved.

Dripping from the drainage port once the bag had been emptied and the device closed occurred frequently; it was attributed to retention of small volumes of urine in the outlet tube. Participants adopted multiple strategies to compensate for this possibility, including wiping the drainage port with toilet paper, or shaking the tube to clear any residual urine. One female respondent commented on how undignified she found having to "*shake off like a bloke*".

The ease of opening and closing of the drainage port was considered an important design feature. Even participants with full dexterity indicated that most drainage ports would pose problems if they were to lose strength, feeling, or dexterity in their fingertips. Criticisms of drainage port operation included being too stiff, too small, requiring too much force to open or close, and lack of a clear indication whether the drainage port was open or closed. Some drainage ports were considered to be too prominent under clothing, or uncomfortable when worn against the leg.

Reaching and accessing the tap to empty the bag was a challenge for some participants. This was affected by individual capability, bag positioning, and clothing choice. For those with movement in their legs, the leg was often positioned on the toilet seat for emptying. This poses difficulties in terms of strength, balance, flexibility and reach. Participants reported emptying into a bottle or jug, rather than directly into a toilet. For women, standing up to drain the bag, as opposed to sitting on the toilet was perceived as defeminising.

Additional Leg Bag Features

Ridged connectors (Figure 1Ai) to secure the leg bag to a catheter or external collection device were preferred by those participants who reported using both systems because it gave a clearer indication of a secure seal and was easier to grip that smooth connectors (Figure 1Aii). Participants reported that the connection often did not feel secure, and there was no clear indication that the connector has been pushed in far enough. Participants generally feared that a connection would fail particularly when moving during sleep, or when getting in and out of the car.

Participants reported using straps or a sleeve to secure their leg bags in position. These methods were not considered secure enough and a better system for securing the bag to the leg was desired, especially among ambulatory users. One participant reported that he could not walk more than 100 yards before the leg bag began to drop down his leg. He specifically

stated, "*I have tried different brands but [they] still didn't hold after the bag is half full –I'm always aware of it*."

Respondents in wheelchairs were more satisfied with the security offered by the straps. In contrast, users who were ambulatory stated the straps were not tailored to mobile, or slim users, and the lack of security rendered exercise difficult. Several ambulatory users suggested that strapping the leg bag above and below the knee (rather than on the lower leg) helped improve security. Participants reported difficulty positioning the securement device so sufficiently tight to prevent slippage, without compromising local blood flow or comfort. Respondents note that some of the strap configurations were complex and hard to manage without assistance. Straps were also associated with bunching of the bag and sagging once the bag filled with urine. Eight respondents reported discomfort from straps cutting into their skin and causing pressure marks due to the required tightness to keep them in place, as well as causing itching and dry skin. Soft, broad straps were preferred.

Sleeve devices for leg bag securement were used less frequently than strap type devices. They were viewed as hard to place on the leg, particularly for users with limited flexibility or paralysis. The reported advantages of the sleeves included the ability to prevent the leg bag from directly against the skin and enhancement of the ability to hide the leg bag under clothing. Several participants described devising their own support aids including safety pinning straps to underwear, adapted underpants and cycling shorts, holsters or belts and cargo trousers with a zip in the back of the pocket to hold the bag.

Connecting Tubing

Leg bag tubing was noted to vary significantly based on characteristics of flexibility and diameter. While larger tubes were regarded as less discrete than smaller ones, they were also perceived to reduce the likelihood of kinks and leaks and provide better drainage. Respondents noted that excess tubing were sometimes visible under clothing. Tubing was

perceived as vulnerable to catching, resulting in separation of connectors and loss of urine containment. Three users and the consultant urologists indicated the use of tape to enhance discretion of the tubing, prevent damage to the catheter site and limit the risk of blockage. Corrugated tubing was considered more flexible and therefore, more discrete and comfortable to wear. Nevertheless, it was also perceived as more likely to be associated with pooling in the tube and to appear dirty on the external surface.

Design Needs

Participants were asked to identify the main thing they would like to change about their leg- bag. Six of the 29 user participants indicated that they were satisfied with the system they used. Priorities for improvements varied; they included improved discretion under clothing, greater security when positioning the bag on the leg, reduced likelihood of loss of urine containment, and enhancements enabling independent use for those with limited mobility or dexterity. Refer to Figure 4 for a comprehensive list of product design priorities for leg bags and their component parts.

Discussion

Findings from this study suggest that leg bag use impacts confidence and ability to engage in multiple daily activities. Design limitations of currently available leg bags were: 1) reliability of the bag, drainage port and connecting tubing to present and connectors to prevent loss of urine containment, 2) leg bag securement, and 3) discretion when worn under clothing. These findings support those of Fader and colleagues[17] who also highlighted the need for inconspicuous and reliable products.

Study findings also led to suggesting for unmet design needs associatged with commercially available products. Innovation in the area of leg-bag design is sparse, probably owing to a variety of factors such as cost of a major leg-bag redesign given the modest number of regular users, and a focus on maintaining compatibility between different products

and components. We believe that collaboration among manufacturers of indwelling catheters, external collection devices, and manufacturers of leg bags is essential. Our findings are consistent with those reported by previous studies that research strongly suggest that currently available leg bag designs do not meet the diverse needs of users.[4,14,17] Additional research is needed to improve leg-bag and accessory design and guide clinicians to develop a tool or guideline to assist for health professionals and users to select specific products

Limitations

The interviews were mainly carried out over the telephone and data recorded by hand. The absence of audio recording technology and verbatim transcripts is an acknowledged limitation of the study. Participants included individuals with a range of physical capabilities; but sampling did not purposively seek out respondents with a range of physical conditions and capabilities. Our recruitment approach may have inadvertently targeted users dissatisfied with current leg-bag designs.

Conclusion

Outcomes of this study enabled identification of multiple functional and design issues associated with regular use of leg-bags for urinary incontinence or retention. These issues included the reliability of leg bags, their visibility under clothing, and ability to secure the bag to the leg. We believe it unlikely that a single product can be designed that will meet the diverse needs of leg bag users. Nevertheless, we believe that data from this study provides insights into design and functional limitations of currently available leg bags and user suggestions for improving this essential component of a urinary drainage system.

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TABLE & FIGURES

Age bracket of leg bag users	Number of participants
35-44 years	2
45-54 years	4
55-64 years	8
65-74 years	10
75+ years	5

Table 1

	Number of participants
Leg bag users	29
Male Female	20 9
Wheelchair users	14
Suprapubic catheter user Urethral catheter user Sheath user	6 8 15
Informal Carers	2
Clinical staff	3

Table 2

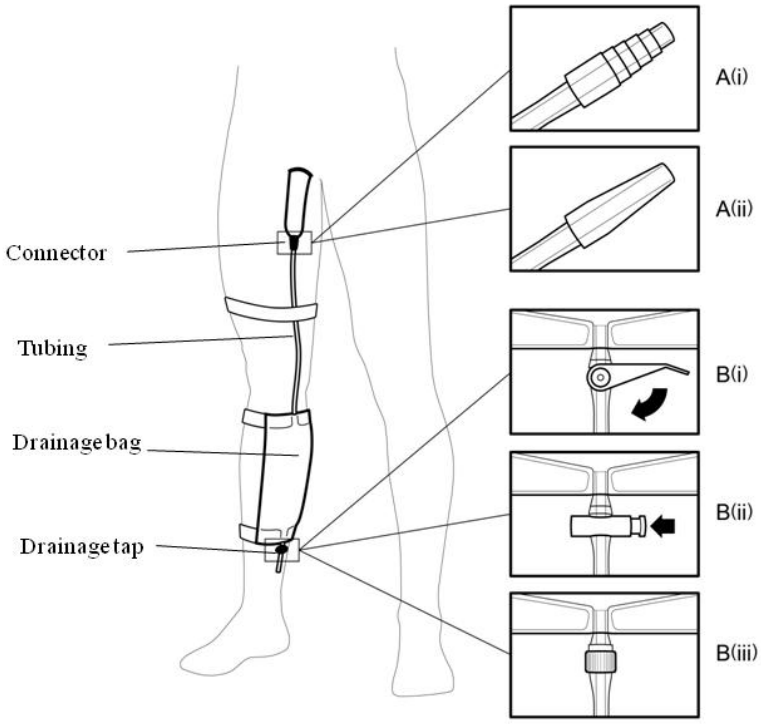
Connector
Tubing
Drainage bag
Drainage tap
A(i)
A(ii)
B(i)
B(ii)
B(iii)

Figure 1

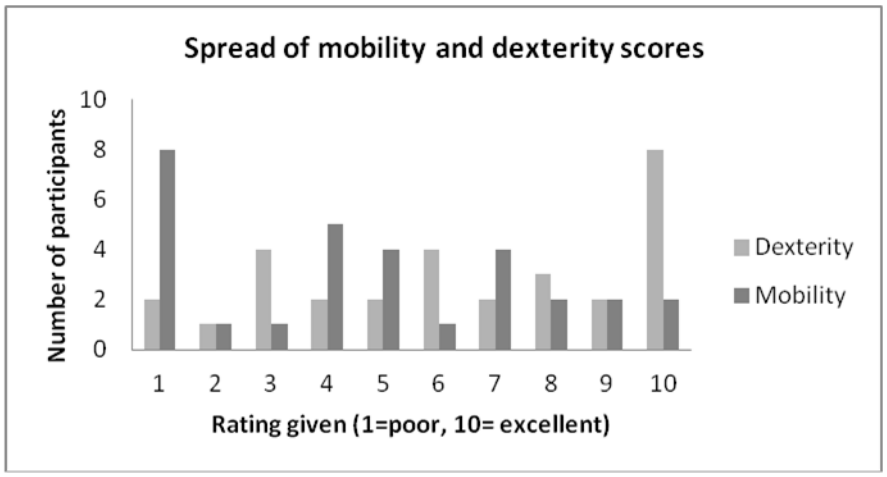
Spread of mobility and dexterity scores
Number of participants
10
8
6
4
2
0
1
2
3
4
5
6
7
8
9
10
Rating given (1=poor, 10= excellent)
Dexterity
Mobility

Figure 2

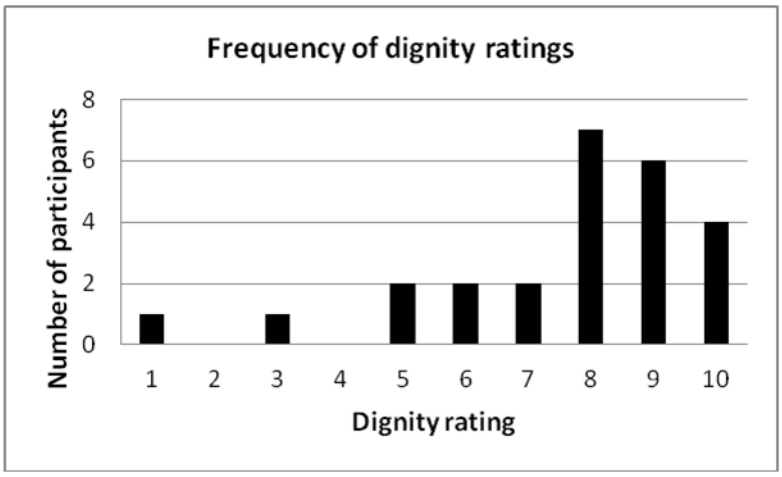
Frequency of dignity ratings
Number of participants
0
2
4
6
8
1
2
3
4
5
6
7
8
9
10
Dignity rating

Figure 3

Taps should...

- not leak
- not drip after bag emptying
- be easy to open and close
- be designed to allow bag drainage without wetting fingers or surfaces
- be positioned so users can reach taps comfortably
- be obviously open or closed, the state of the tap should be possible to clarify from visual inspection even for those with poor eyesight.
- be secure against accidental opening
- be secure against accidental failure to close
- be able to be operated with one-hand
- be able to be left open for overnight drainage, and be comfortable against the body
- be inconspicuous and discrete under clothing

Connectors should...

- allow quick, easy and secure connection and removal of components
- prevent accidental disconnection
- not be separate items, but incorporated into system design
- be compatible with a variety of products
- be designed to allow changing of bags without wetting fingers or surfaces

Methods of attachment should...

- be comfortable, with wide straps if used
- secure bags firmly in place
- support the weight of a full bag
- allow ease attachment and removal from the body
- prevent pulling on the catheter site or sheath
- allow user choice in bag positioning
- allow user access to the bag
- maintain good blood flow in the leg

Bags systems should...

- be leakage free
- be designed to reduce noise from urine moving (slosh) and entering the bag
- be discrete under clothing
- minimise odour
- be made of material that does not rustle
- incorporate components to allow quick filling, emptying, sampling and prevent urine backflow
- be designed to resist kinking and twisting of tubing
- be available in different sizes
- be designed to prevent skin irritation and reduce slippage
- ensure all components are made from materials that can be sterilised
- allow easy drainage into standard height toilets
- be easily disposed of
- recyclable components and packaging should be clearly labelled
- packaged for ease of opening with limited dexterity

Figure 4

Figure 1
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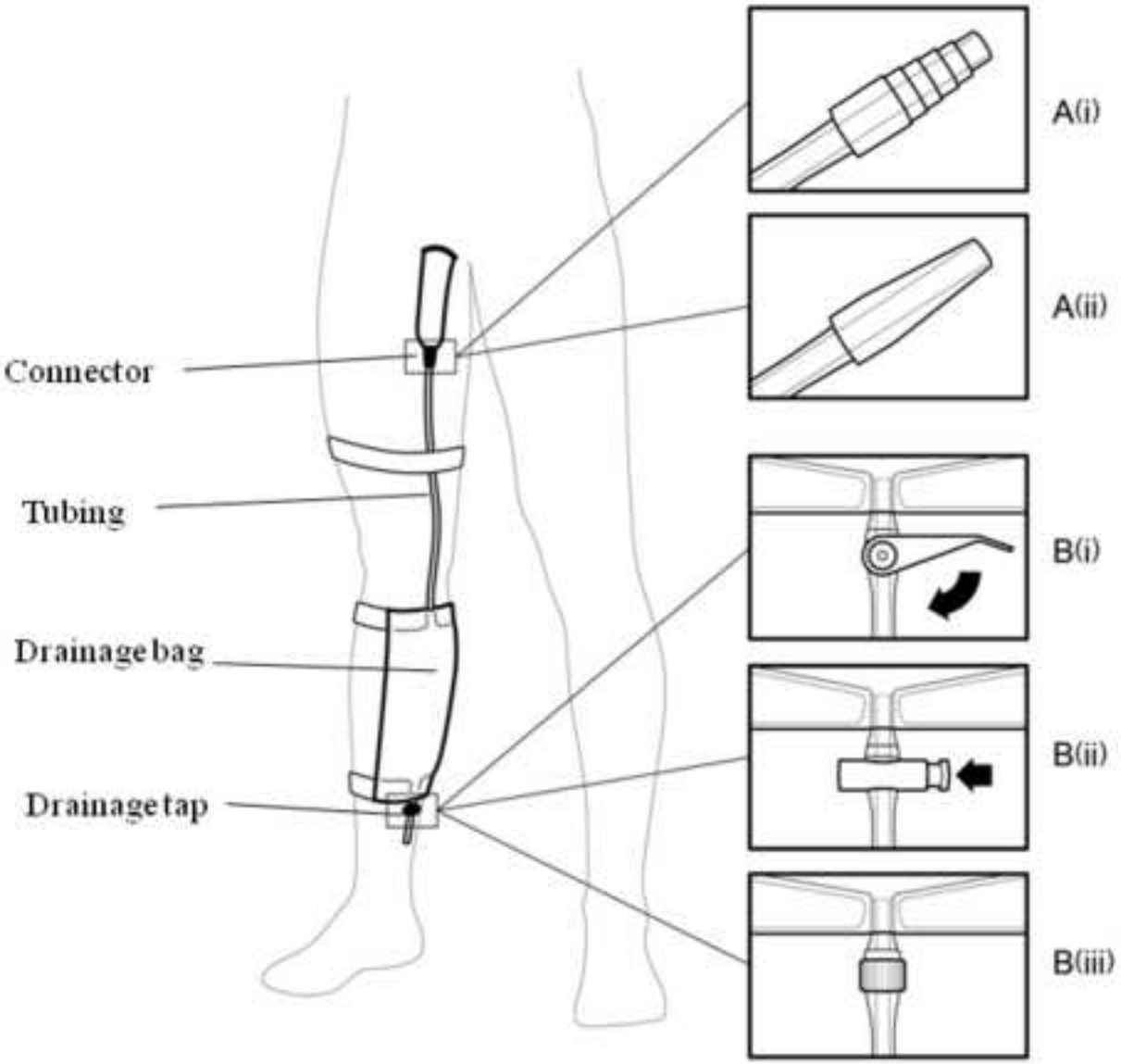

Figure 2
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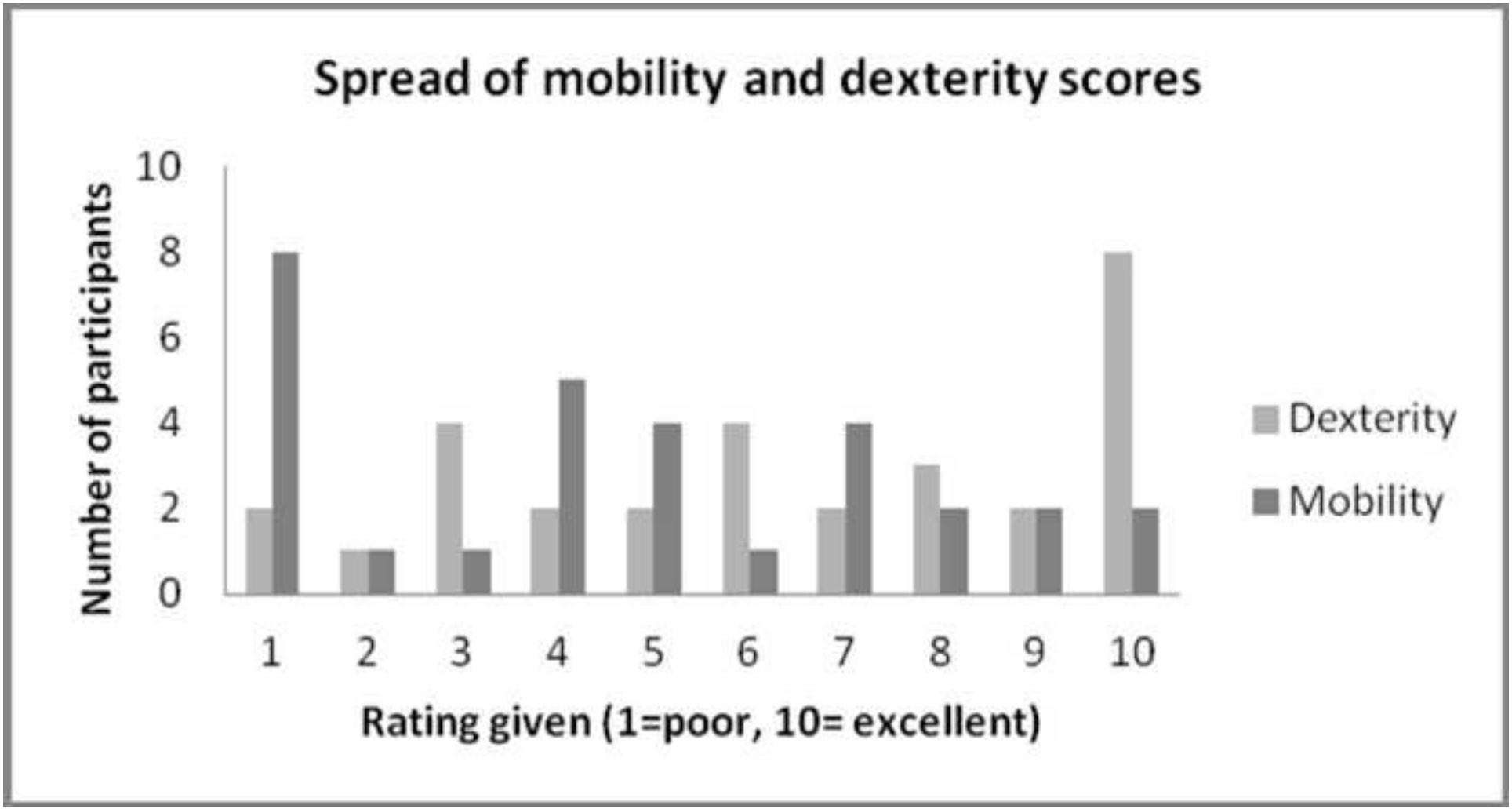

Figure 3
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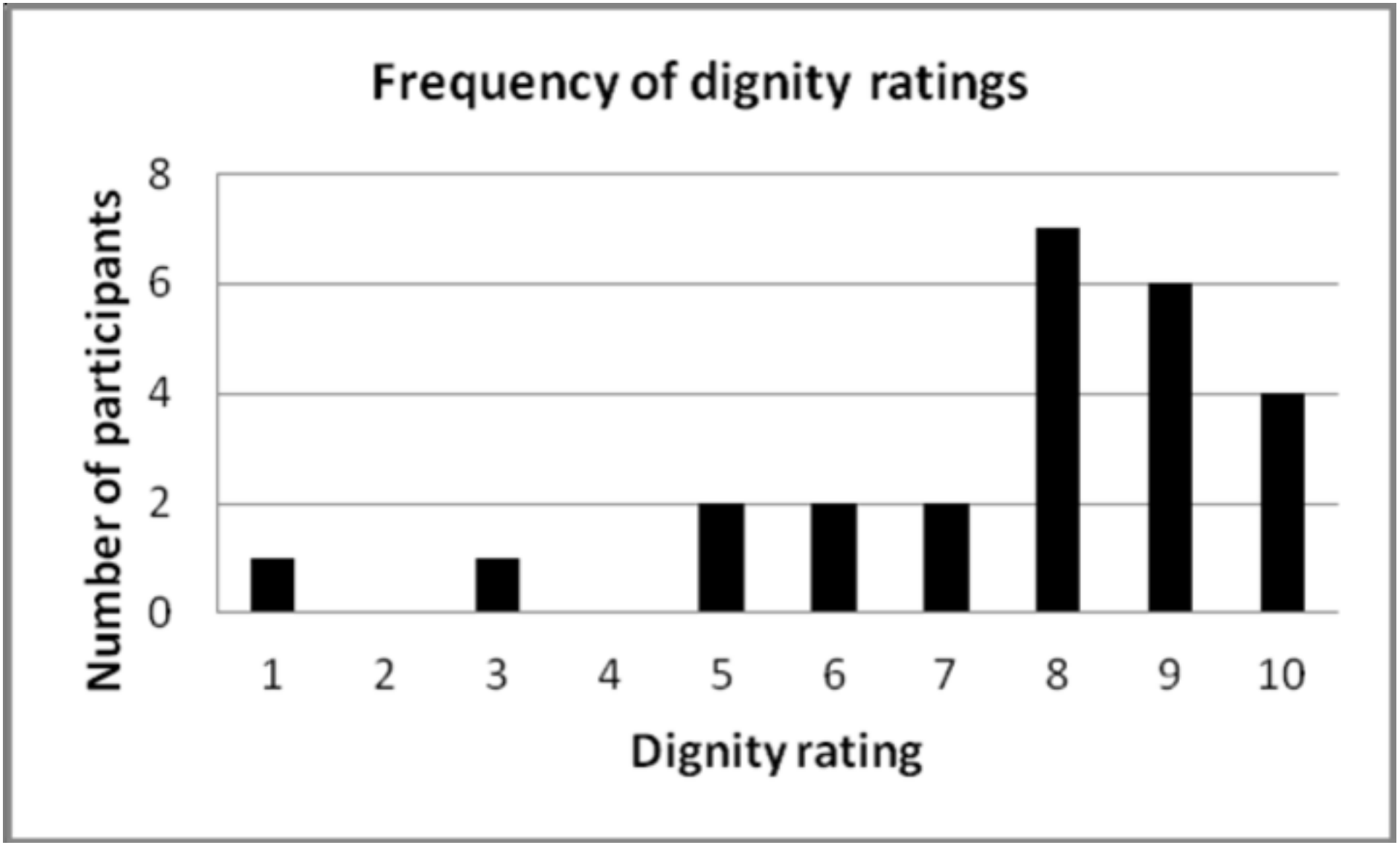

Figure 4
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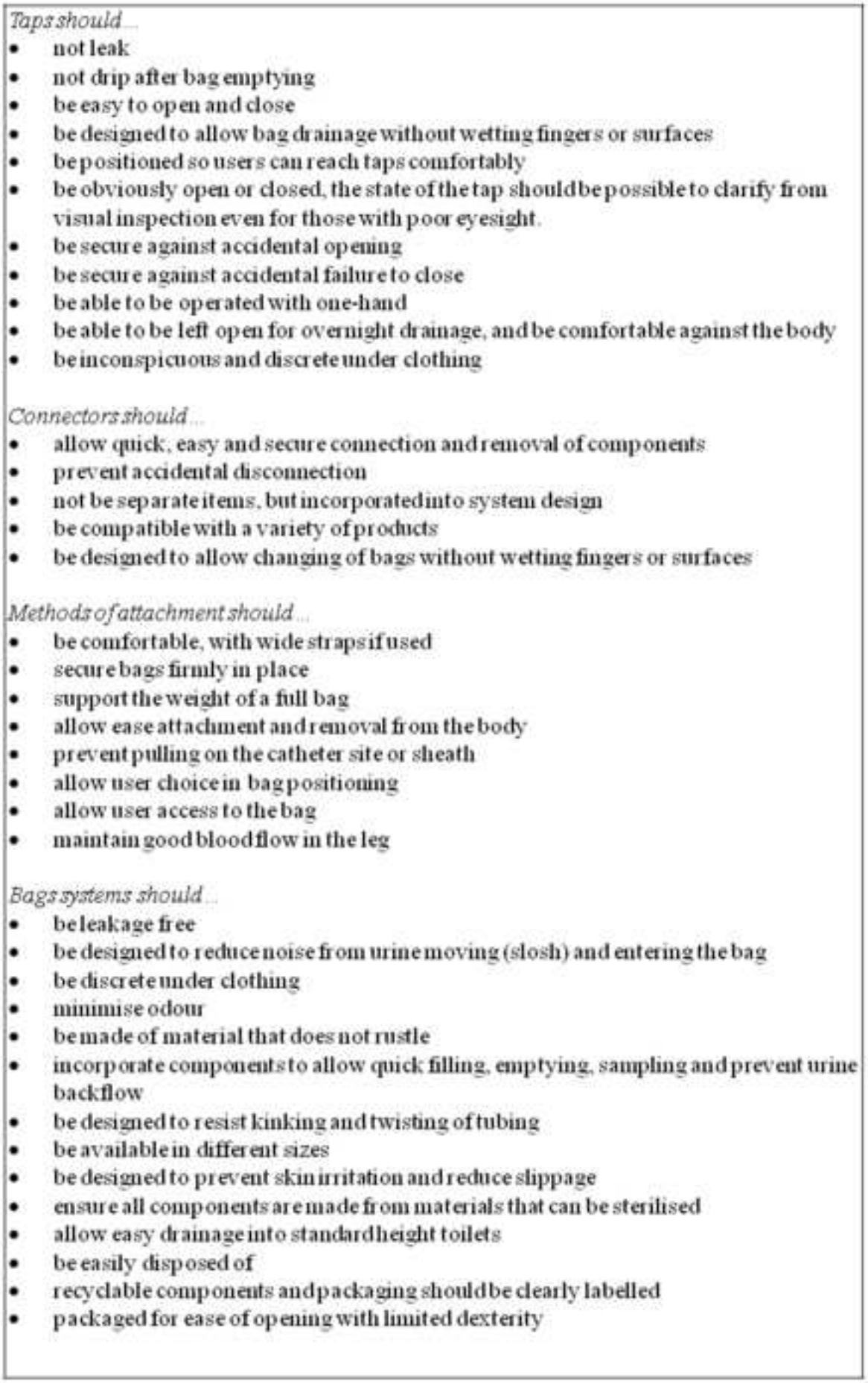

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TITLE PAGE

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Experiences of leg bag users and emerging design priorities

Author names, degrees and affiliations
Louise MOODY, BSc (Hons), PhD.
Centre of Excellence in Product and Automotive Design, Department of Industrial Design

Avril MCCARTHY, BSc (Hons), PhD, HPC Registered Clinical Scientist
Sheffield Teaching Hospitals NHS Foundation Trust and NIHR Devices for Dignity Healthcare Technology Co-operative

Corresponding author
Louise MOODY
Department of Industrial Design
Coventry University
Priory Street
Coventry CV1 5FB
Email: L.moody@coventry.ac.uk
Tel: +44 2476 795601 / +44 7970 732811
Fax: +44 2476 888667

Address for reprints – as above

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